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EXAMINER

CHAPMAN, GINGER T

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,450	Applicant(s) MULLEJANS ET AL.	
	Examiner Ginger T. Chapman	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 25-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/11/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Claims

1. Claims 1-31 are amended, claims 1-31 are pending in the application.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, Claims 1-24, drawn to a disposable inner bag liner comprising an open end having an annular first flange, a first hole for receiving a stoma, ureter or catheter, a first adhesive surface, and a second surface and an outer receiving member comprising a second hole for receiving a stoma, ureter or catheter, and a second flange, and with a release liner, wherein the release liner comprises gripping means.

Group 2, Claims 25-27, drawn to an ostomy appliance comprising a base plate comprising a base plate having a third hole, an adhesive wafer, a receiving member and a bag liner.

Group 3, Claims 28-31, drawn to method of applying an inner bag liner to a receiving member.

3. The inventions listed as Groups 1 through 3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

4. 1. Where the group of inventions is claimed in one and the same international application, the requirement for unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “**special technical features**” shall mean those technical features that define a contribution which **each of the claimed inventions** considered as a whole, **makes over the prior art**. The inventions listed as Groups 1 and 2 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they do not share a special technical feature. The special technical feature of Group 1 is a liner having an open end having an annular first flange comprising a first hole for receiving a stoma, ureter or catheter and an outer member comprising a second hole for receiving a stoma, ureter or catheter and a second flange and an adhesive and a release liner and the release liner

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comprises gripping means; the special technical feature of Group 2 is an ostomy appliance base plate and a wafer member configured to be attached to a wearer; the special technical feature of Group 3 is a method of applying a bag liner to a receiving member. Group 1 does not share the special technical feature of Groups 2-3 because, respectively, Group 1 does not require a base plate and wafer; and does not require a method of applying a liner to a receiving member, and instead the bag liner can be used as a stand alone product or as a liner for a surgical fluid basin. Group 2 does not share the special technical feature of Group 1 and Group 3 because Group 2 does not require, respectively, a bag liner having an open end having an annular first flange comprising a first hole for receiving a stoma, ureter or catheter and does not require an outer receiving member comprising a second hole for receiving a stoma, ureter or catheter and a second flange; does not require being applied to a receiving member because it can be used as a stand-alone wafer for ostomy bags without liners and because the base plate and wafer can be used with a conventional ostomy bag that does not have an inner liner and can also be used to secure a catheter or gastroenterology tube to a wearer. Group 3 does not require the special technical features of Groups 1-2 because Groups 1-2 can be used as teaching or demonstration models and because Groups 1-2 do not have to be applied to each other but can be used as noted *supra*.

5. The special technical feature of Group 1 does not define a contribution over the prior art for the following reasons: Claim 1 is either obvious or anticipated by any one of the following: US 5,785,695; US 5,865,819, each individually. Accordingly, the special technical feature linking the inventions, a liner, does not provide a contribution over the prior art, and no single general inventive concept exists. Therefore the restriction is appropriate.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. During a telephone conversation with Ms. Susan Bailey on March 4, 2010 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-24. Affirmation of this election must be made by applicant in replying to this Office action. Claims 28-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim language interpretation

9. The term “release liner” in claims 1, 5-11, 14, 15, -21 and 24 is used by the claim to mean “a flange”, while the accepted meaning in the art is that a “release liner” comprises a paper or plastic material coated with a release agent to cover and protect an adhesive prior to use and which is peeled from the adhesive and discarded. Release liners are known in the art as paper or plastic based web carrier material which is coated on one or both sides with silicone or other low surface energy coating; the release liner is used to cover and protect adhesive on products from premature adhesion; such that release liners are generally peeled from the adhesive and discarded

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when the user desires to adhere the adhesive to another surface (source: Wikipedia online encyclopedia).

10. The instant Specification, in particular at [0012-0020, 0088, 0089, 0101, 0104, 0106], in particular at paragraph [0019], discloses that the instant claimed release liner is provided as a disc-like flange structure comprising protrusions and is intended to perform as a flange which is interposed between adjacent flanges of an ostomy appliance and remains therebetween while the appliance is in use. It is noted that the claim language "release liner" has not been specifically defined by Applicants and thus will be given its broadest customary interpretation, i.e. the dictionary definition, in light of the Specification.

11. Therefore the instant claimed "release liner" is being interpreted as a flange with alignment elements interposed between adjacent flanges in use.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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14. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato et al (US 5,785,695) in view of Cisko, Jr. et al (US 5,865,819).

15. With respect to claim 1, as best depicted in Figures 4-7, Sato discloses a disposable inner bag liner 15 for an ostomy appliance, the inner bag liner 15 being capable of forming a bag inside an outer receiving member 10, said outer receiving member 10 having a hole 11 for receiving a stoma, ureter, or catheter for receiving effluents or waste products of the body, and a flange 7, said disposable inner bag liner 15 comprising: an open end 16 having an annular flange 22 that includes a hole (fig. 6) for receiving a stoma, ureter or catheter for receiving effluents of waste products of the body, a first surface (figs. 5-7) being provided with an adhesive 151 and a release liner 22, and a second surface 23 (fig. 6); said outer receiving member 10 flange 7 and the second surface 23 of the liner 22 being adapted to be releasably adhered to each other (fig. 6); and said release liner 22 on said first surface including an alignment element 23 for aligning the inner bag liner 15 flange 22 in relation to the outer receiving member flange.

16. Sato discloses the claimed invention except for explicitly disclosing the liner is a release liner. The examiner notes that the instant claimed "release liner" is not a conventional release liner, i.e. a paper or plastic strip which covers an adhesive and which is peeled off and discarded prior to adhering the adhesive to another surface; but rather the instant claimed "release liner" is a flange structure with alignment elements, said instant claimed "release liner" is substantially identical to the flange structure with alignment elements disclosed by Sato. Sato discloses the first surface of the inner bag liner provided with an adhesive and including an alignment element substantially identical to the instant claimed "release liner" for aligning the inner bag liner in relation to the outer receiving member flange. Sato discloses that the surface adhesive and

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alignment element perform the substantially identical function as the claimed function of releasably adhering the outer receiving member flange and the second surface of the liner, as the instant claimed adhesive, release liner and alignment element; thus Sato discloses the flange and second surface and alignment element are capable of performing the claimed function as the release liner alignment element with the substantially identical result.

17. In the alternative, Cisco, at column 2, lines 51-62, provides motivation release liners. As best depicted in Figure 3, Cisco teaches an inner bag liner 12 having a first surface 14 provided with adhesive and a release liner 15 (column 3, line 23, lines 28-32 and lines 45-47). therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the surface of Sato with a release liner as taught by Cisco since Cisco states, at column 4, lines 23-37 and lines 51-62, that the benefit of forming the inner bag liner with this design is that the release liner protects the adhesive and thereby permits an outer receiving member and a second surface of the inner bag liner to be adhered to each other when aligned.

18. With respect to claim 2, as best depicted in Figure 6, Sato discloses the disposable inner bag liner 15 wherein the first alignment element 23 is adapted to align the hole 16 in the inner bag 15 liner to be substantial concentric in relation to the hole 11 in the outer receiving member 10 (column 9, line 49). See also Cisco at column 4, lines 24-37.

19. With respect to claim 3, as best depicted in Figure 6, Sato discloses the disposable inner bag liner 15 wherein the alignment element 23 is adapted to align the flange 22 on the inner bag liner to be substantially concentric in relation to the flange 7 on the outer receiving member 10 (column 9, line 49). See also Cisco at column 4, lines 24-37.

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20. With respect to claim 4, Sato discloses the disposable inner bag liner 15 wherein the flange 7 on the outer receiving member 10 is provided with an additional alignment element 21 adapted to co-operate with the alignment element 23 on the release liner 22 (fig. 6).

21. With respect to claim 5, Sato discloses the disposable inner bag liner 15 wherein the alignment element 23 on the release liner 22 is adapted to engage the additional alignment element 21 on the outer receiving member 7 (fig. 6).

22. With respect to claim 6, Sato discloses the claimed invention except for the release liner defines a protrusion. Sato discloses the embodiment wherein the outer member defines a protrusion and the release liner defines an indent which engages the protrusion on the outer member, disclosed in the instant Specification at paragraph [0017] and in claim 6, *infra*, as a suitable embodiment of the instant claimed invention, thus Sato provides motivation for one component to define a protrusion which engages a mating recess on the other member with the substantially identical effect of providing engagable mating members. Therefore it would have been obvious to one having ordinary skill at the time the invention was made that the protrusion could be provided on either the release liner or the mating member with the substantially identical result since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

23. With respect to claim 7, Sato discloses the inner bag liner 15 wherein the alignment element 23 on the release liner 22 defines a recess and/or hole (fig. 6) adapted to be engaged by the additional alignment element 21 on the outer receiving member 7 (fig. 6).

24. With respect to claim 8, Sato discloses the claimed invention except for the additional alignment element on the outer receiving member defines a recess and/or hole adapted to be

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engaged by the alignment element on the release liner. Sato discloses the embodiment wherein the additional alignment element 23 on the release liner 22 defines a recess and/or hole adapted to be engaged by the alignment element 21 on the outer receiving member 7, thus providing motivation for the outer receiving member and the release liner to be engaged wherein the only difference is the alignment elements are on the opposite components, disclosed in the instant Specification at paragraph [0017] and claims 7 and 9 as a suitable embodiment of the instant claimed invention. Therefore it would have been obvious to having ordinary skill in the art at the time the invention was made to provide the recess on either the release liner or on the outer receiving member since it appears that the invention would work equally well with the alignment elements on either component and since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

25. With respect to claim 9, as best depicted in Figure 7, Sato discloses the embodiment wherein the alignment element on the release liner defines an alignment leg 6 that protrudes from at least a part of an outer rim 41 of the flange 22 on the inner bag liner and/or the release liner (col. 9, lines 45-55).

26. With respect to claim 10, Sato discloses wherein the alignment leg 6 protrudes along the entire outer rim of the flange 41 on the inner bag liner (col. 9, lines 45-55).

27. With respect to claim 11, Sato discloses the alignment element 23 on the release liner 22 has a geometrical shape indicating a corresponding shape 21 of the flange 7 on the outer receiving member 10 (col. 4, lines 1-6). See also Cisco at column 4, lines 22-35.

28. With respect to claim 12, Sato discloses the claimed invention except for the geometric shape protrudes from the inner bag liner flange. Sato discloses the geometric shape protrudes

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from the outer member flange, thus providing motivation for a geometric shape permitting the flanges to be engaged, disclosed in the instant Specification at paragraph [0017] as a suitable embodiment of the instant claimed invention. Therefore it would have ordinary skill in the art at the time the invention was made to provide the geometric shape protrudes from either the release liner or on the outer receiving member since it appears that the invention would work equally well with the geometric shape on either component and since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

29. With respect to claim 13, Sato discloses the claimed invention except for the geometric shape defines a line on the surface of the inner bag liner. As best depicted in Figure 4, Cisko teaches the geometric shape defines a line 14 (col. 4, lines 27) on the surface of the inner bag liner. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the shape of Sato defining a line as taught by Cisko since both shapes perform the substantially identical function of permitting the members to be aligned and Cisko states, at column 4, lines 24-37, that the benefit of forming the liner with this design is that the geometric line provides a geometric outline which permits the inner bag liner to be aligned with the outer receiving member.

30. With respect to claim 14, Sato discloses the claimed invention except for expressly disclosing the release liner includes a gripping element. Sato discloses the release liner 22 comprises surfaces that permit the liner 22 to be manipulated to adhere to outer receiving member 10 flange 7, thus the release liner inherently comprising a gripping surface. Sato further discloses the mating flange 1 includes a gripping element 42 (col. 9, lines 57-60), thus providing motivation for a gripping element and Sato discloses the gripping element can be provided on

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either of the flanges (col. 9, lines 60-62). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the gripping element on either the liner or the mating flange since both locations provide a gripping element for the user and Sato states, at column 9, lines 57-62, that the benefit of forming the ostomy appliance with this design is that the flanges can be fitted to each other easily by the user inserting a finger behind the gripping element and the gripping element can be provided on the other flanges, and since it has been held that rearranging parts of an invention involves only routine skill in the art.

In re Japikse, 86 USPQ 70.

31. With respect to claim 15, Sato discloses the claimed invention except for the gripping element protrudes from an outer rim of the release liner (col. 9, lines 57-60). Sato discloses the gripping element 42 protrudes from an outer rim of mating flange 1, thus providing motivation for a gripping element protruding from one of the flanges and Sato discloses the gripping element can be provided on either of the flanges (col. 9, lines 60-62). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the gripping element on either the liner or the mating flange since both locations provide a gripping element for the user and Sato states, at column 9, lines 57-62, that the benefit of forming the ostomy appliance with this design is that the flanges can be fitted to each other easily by the user inserting a finger behind the gripping element and the gripping element can be provided on the other flanges and since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

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32. With respect to claim 16, Sato discloses a gripping plane defined by at least part of the gripping element 42 is transverse to a liner plane defined by at least part of the release liner provided inside the outer rim (fig. 7; col. 9, lines 46-60).

33. With respect to claim 17, Sato discloses the gripping plane and the liner plane define an angle of between 5 to 45 degrees (fig. 7).

34. With respect to claim 18, Sato discloses the claimed invention except for the gripping element protrudes from a surface of the release liner. Sato discloses the gripping element 42 protrudes from a surface of mating flange 1, and can be provided on the other flanges, thus providing motivation for a gripping element. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the gripping element on either the liner or the mating flange since both locations provide a gripping element for the user and Sato states, at column 9, lines 57-60, that the benefit of forming the ostomy appliance with this design is that the flanges can be fitted to each other easily by the user inserting a finger behind the gripping element and since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

35. With respect to claim 19, Sato discloses the gripping element 42 defines at least two gripping surfaces so as to allow gripping of the flanges with two fingers (col. 9, lines 51-53, teaching the gripping element is concentric and therefore fully capable of being gripped with two fingers on the opposed sides of the flange).

36. With respect to claim 20, Sato discloses the gripping surfaces 42 are transverse to a liner plane defined by at least a part of the release liner (fig. 7).

37. With respect to claim 21, Sato discloses the gripping surfaces 42 are concave (fig. 7).

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38. With respect to claim 22, as best depicted in Figures 5 and 6, Sato discloses the embodiment wherein a compartment 16 projecting 7 from the liner 15, the compartment 16 defining gripping surfaces 7.

39. With respect to claim 23, Sato discloses the claimed invention except for the closed end of the inner bag liner in a compacted state is provided with a cover. As best depicted in Figures 6-8, Cisko discloses the closed end of the inner bag liner 12 in a compacted state is provided with a cover 23. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide bag of Sato with a cover as taught by Cisko since Cisko states, at column 6, lines 49-65, that the benefit of providing a cover is that it protects the inner bag and can be removed when separating the inner bag from the outer bag receiving member.

40. With respect to claim 24, Sato discloses the claimed invention except for the release liner is provided with a protection film placed at an opposite side of the release liner in relation to the cover. As best depicted in Figures 3 and 6-8, Cisko discloses a release liner 14 on the first surface of the inner bag and a protection film 21 placed at the opposite side of the release liner in relation to the cover 23. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the release liner of Sato with a protection film as taught by Cisko since Cisko states, at column 4, lines 51-60, that the benefit of providing a protection film over the release liner is that it protects the adhesive of the liner until removed to adhere the inner bag liner with the outer receiving member.

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Conclusion

41. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

42. Pedersen et al (US 2005/0113770 A1) Figures 2-3, 8-10, 13-14; Gilchrist et al (US 4,816,027) Figure 2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/

Examiner, Art Unit 3761

03/12/10

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761